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10/626,379	07/24/2003	Gregory E. Amidon	PC27516A	9809

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,379	AMIDON ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,22-30,37 and 48-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12, 22-30, 37 and 48-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed on July 7 2008 is acknowledged. Claims 13-21, 32-34, 36 and 38-47 were/stand cancelled. Claims 1-3, 5-7, 10-12, 22-25, 30 and 37 amended. Claims 48-58 were added. Claims 1-12, 22-31, 35, 37 and 48-58 are pending. Claims 31, 35 are withdrawn as being directed to a non-elected invention. Claims 1-12, 22-30, 37 and 48-58 are directed to the elected invention.

Abstract

The objection of the abstract is **withdrawn** in light of Applicants' amendments to abstract filed on July 7 2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-30 and 37-41 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in light of Applicants' amendments filed on July 7 2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-3, 13-14 under 35 U.S.C. 102(b) as being anticipated by Kitamori et al. (US Patent No. 4036948) is **withdrawn** in light of Applicants' amendments filed on July 7 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12, 26, 29 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandecruys et al. (WO 00/59477, cited on PTO Form 1449).

Applicant Claims

Applicant claims a composition comprising reboxetine dispersed in a matrix comprising a hydrophilic polymer and a starch having a tensile strength of at least 0.15 kN/cm^2.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The formulations of the invention comprise active ingredients, viscous hydrophilic polymer(s), pregelatinized starch, and pharmaceutically acceptable formulating agents (page 20-21, lines 21-36 and 1-25). One formulation is where the hydrophilic polymer is hydoxypropyl cellulose and is present in an amount from 25-62% (page 21, line 22). This percentage anticipates instant claims 10 and 11. Other percentages disclosed are from 0.01-80% (page 20, line 23). The pregelatinized starch is present in an amount from 0.01 -<80% (page 20, line 24). It is disclosed that the most preferred hydrophilic polymers are hydroxypropyl methylcellulose and hydroxypropyl cellulose (page 12, lines 12-13). It is disclosed that the formulations of the invention are useful for administering one or more active ingredients (page 6, lines 31-32). Suitable active ingredients include antidepressants such as reboxetine (page 7, line 16), setraline (page 7, line 18), or 3-[2-

[3,4-dihydrobenzofuro[3,2-c]pyridine-2(1H)-yl]ethyl]-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one (page 7, lines 18-19 and examples 3-4), and their pharmaceutically acceptable salts or their stereochemically isomeric forms.

It is disclosed that the tablets of the invention are preferably film coated. The coatings can serve purposes such as improving stability and shelf-life or improving taste or ease to which the tablet can be swallowed (page 23, lines 30-33).

It is disclosed that the formulation is prepared by mixing one or more actives, pregelatinized starch, one or more hydrophilic polymers, and optionally some or all of the pharmaceutically acceptable formulating agents. The mixture is then tabletted using direct compression (page 22, lines 37-38). The resulting tablets are manufactured from a homogenous dispersion of the above mentioned ingredients (page 23, lines 19-20).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

While Vandecruys et al. exemplifies utilizing antidepressants in the tablet formulations of the invention, Vandecruys et al. does not exemplify utilizing the antidepressants reboxetine or a combination of reboxetine and sertraline. However, Vandecruys et al. does indicate that reboxetine and sertraline are suitable.

Vandecruys et al. does not exemplify the claimed starch or hydrophilic polymer ranges. However, Vandecruys et al. does disclose overlapping ranges.

Vandecruys et al. does not specify selecting by a suitable test a starch.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to utilize reboxetine or its salt or enantiomer thereof as the active ingredient in the invention of Vandecruys et al. One of ordinary skill in the art would have been motivated to utilize reboxetine, an antidepressant, because Vandecruys et al. exemplifies utilizing as the active ingredient a different antidepressant, 3-[2-[3,4-dihydrobenzofuro[3,2-c]pyridine-2(1H)-yl]ethyl]-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one. Therefore it would have been obvious to one of ordinary skill in the art to substitute one known antidepressant for another antidepressant. One of ordinary skill in the art would have been motivated to select reboxetine as the antidepressant from all known other antidepressants because Vandecruys et al. indicate that it is suitable. One of ordinary skill in the art would have been motivated to utilize the salt or enantiomer because Vandecruys et al. discloses that salts and stereochemically isomeric forms are suitable. It would have been obvious to one of ordinary skill in the art to pursue known options within his or her technical grasp, specifically salts or stereochemically isomeric forms of the active ingredients.

It would have been obvious to one of ordinary skill in the art to utilize reboxetine and sertraline as the active ingredients in the invention of Vandecruys et al. One of ordinary skill in the art would have been motivated to utilize this combination because Vandecruys et al. discloses that one or more active ingredients can be utilized. Additionally Vandecruys et al. exemplifies utilizing an antidepressant as the active. Therefore, one of ordinary skill in the art would have been motivated to replace one antidepressant for another antidepressant, such as reboxetine or sertraline.

As a general principle it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06.**

Therefore, absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Regarding the limitation of the tensile strength, Vandecruys et al. is silent as to the tensile strength of the starch. However, the starches utilized by Vandecruys et al. are the same starches claimed in the instant application, pregelatinized starches. Therefore, absent evidence to the contrary, the examiner believes that the starches disclosed by Vandecruys et al. would have the same if not similar tensile strength.

Regarding the claimed ranges of starch (claims 4-7) and the claimed ranges of hydrophilic polymer (claim 12), Vandecruys et al. discloses overlapping ranges. In the case where in the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **See MPEP 2144.05 [R-5]**

Regarding claim 37, it would have been obvious to one of ordinary skill in the art to choose a particular starch or a particular active pharmaceutical agent based on the desired properties of the tablet. The only starch utilized by Vandecruys et al. is the

preferred starch of the instant application. The selection of a suitable starch as well as the selection of an active pharmaceutical is an implicit step in the formulation of an active-containing tablet. Therefore, the process for preparing the composition of Vandecruys et al. is the same as that instantly claimed.

Response to Arguments

Applicants argue that (1) Vandecruys et al. address an entirely different formulation problem. Applicants argue that (2) not all the pregelatinized starches disclosed by the Vandecruys Reference would have the same or similar tensile strength. Applicants argue that (3) pregelatinized starches not meeting the tensile strength criterion are not readily identified without testing. Applicants argue that (4) starches from different plant sources differ in their amylose/amylopectin ratio and that these differences modify the physical properties such that the various types "may not" be interchangeable. Applicants present examples that show the variability in both the physical properties of starches. Example 3 shows that two of the six pregelatinized starch lots were found o be unsuitable for tableting.

Applicants' arguments filed July 7 2008 have been fully considered but they are not persuasive.

Regarding applicants' first argument, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Regarding applicants' second and third argument, it does not appear that the applicants' are indicating that none of them have the same or similar tensile strength as instantly claimed just that some may not. Applicants claim pregelatinized starch, which is exactly what Vandecruys et al. teach. Applicants' have provided no factual evidence that none of the pregelatinized starches taught by Vandecruys et al. would possess the instantly claimed tensile strength. Given the fact that applicants have indicated that the tensile strength can not be determined without testing, there is no way for the examiner to determine if the pregelatinized starch taught by Vandecruys et al. possess the same instantly claimed tensile strength. It appears that applicants are attempting to claim a new and/or undiscovered property of an old composition. The examiner directs applicant's attention to MPEP 2112, section I: "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In instant case, the fact that applicant has recognized the tensile strength of pregelatinized starch is not patentably distinguishable since the prior art teaches the same composition as claimed and applicant is merely attempting to claim an unrecognized property of the prior art.

Regarding applicants fourth argument, the instant specification teaches starches that are useful include those from **any** botanical source (paragraph 0059). Therefore, the instant specification teaches that the pregelatinized starch can be from any source including those listed by Vandecruys et al.

Regarding the examples presented, while two of the six pregelatinized did not possess the required tensile strength, four of them did. That means that these starches would necessarily meet the instant limitations. Since the applicants' have provided no information regarding the manufacturer of these starches, it is unclear to the examiner if these are or are not the same as those taught by Vandecruys et al.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Claims 22-25, 30, 37 and 48-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandecruys et al. in view of Rogosky et al. (US PGPUB No. 2002/0010216, cited in the Office action mailed on March 14 2008).

Applicant Claims

Applicant claims that active pharmaceutical agent is therapeutically effective at a daily dose not greater than 100 mg (50 or 25 or 10 or 5mg).

Applicant claims that the pharmaceutical agent is (S,S)-reboxetine succinate.

Applicant claims that the tablet comprises about 0.2 to about 15 mg (about 1 to about 12 mg) reboxetine per tablet.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Vandecruys et al. are set forth above. Vandecruys et al. indicates that reboxetine and sertraline are suitable active ingredients.

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Vandecruys et al. does not specify that the reboxetine is (S,S)-reboxetine succinate. Vandecruys et al. does not specify the dosage of reboxetine that are suitable. Vandecruys et al. does not specify the combination of (S,S)-reboxetine succinate and sertraline. However, these deficiencies are cured by Rogosky et al.

Rogosky et al. indicates that when the preferred compound of use is based, for example reboxetine, pharmaceutically acceptable salts include succinate (paragraph 0030). It is also indicated that the (S,S) enantiomer is particular preferred (paragraph 0031). The dosage of reboxetine is from about 0.1 mg to about 10 mg. The daily dosage is administered in one, two, or more times a day (paragraph 0033).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Vandecruys et al. and Rogosky et al. and utilize (S,S)-reboxetine succinate as the active ingredient. One of ordinary skill in the art would have been motivated to utilize (S,S)-reboxetine succinate because Rogosky et al. indicates that the (S,S) enantiomer is the preferred enantiomers. Additionally Rogosky et al. indicates that one type of pharmaceutical salt of reboxetine that is suitable is succinate. It would have been obvious to one of ordinary skill in the art to pursue known options within his or her

technical grasp, specifically the pharmaceutically acceptable salts and (S,S) enantiomer of reboxetine.

It would have been obvious to one of ordinary skill in the art to utilize (S,S)-reboxetine succinate and sertraline as the active ingredients in the invention of Vandecruys et al. One of ordinary skill in the art would have been motivated to utilize this combination because Vandecruys et al. discloses that one or more active ingredients can be utilized. Additionally Vandecruys et al. exemplifies utilizing an antidepressant as the active. Therefore one of ordinary skill in the art would have been motivated to replace one antidepressant for another antidepressant, such as reboxetine or sertraline. As a general principle it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06.**

It would have been obvious to one of ordinary skill in the art to combine the teachings of Vandecruys et al. and Rogosky et al. and utilize a dosage of reboxetine from 0.1 to 10 mg. One of ordinary skill in the art would have been motivated to select one of these particular dosages because Rogosky et al. indicates that these are the dosages that are effective.

Therefore, absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing

the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that the underlying deficiencies of the Vandecruys et al. reference when relied upon as a basis for the 103 rejection still remain.

Applicants' arguments filed July 7 2008 have been fully considered but they are not persuasive.

The examiner disagrees with applicants' arguments regarding the deficiencies of the Vandecruys et al. reference for the reasons stated above.

Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandecruys et al. in view of Glinecke et al. (US Patent No. 6451343, cited on the Office action mailed on March 14 2008).

Applicant Claims

Applicant claims that the coating on the tablet is a release-controlling layer and constitutes about 1 to about 15% by weight of the tablet.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Vandecruys et al. are set forth above. Vandecruys et al. indicates that the tablets can be coated.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Vandecruys et al. does not specify that the coating is a release-controlling. However, this deficiency is cured by Glinecke et al.

Glinecke et al. discloses that controlled release dosage forms are advantageous. Controlled release formulations requires dosing only once a day, this type of formulation is likely to improve compliance in patient population (column 1, lines 29-32). The controlled release coatings are polymer coatings made from ethylcellulose and opadry clear in 4-5% by weight of the tablet (example 3).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Vandecruys et al. and Glinecke et al. and utilize a controlled release formulation in an amount from 4-5% by weight of the tablet. One of ordinary skill in the art would have been motivated to utilize this type of coating because it is known in the art that controlled release formulations using coatings improve patient compliance by providing once a day formulations. It would have been obvious to one of ordinary skill in the art to utilize the coating in 4-5% by weight of the tablet because Glinecke et al. discloses that is an acceptable percentage for these types of controlled release coatings.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that the underlying deficiencies of the Vandecruys et al. reference when relied upon as a basis for the 103 rejection still remain.

Applicants' arguments filed July 7 2008 have been fully considered but they are not persuasive.

The examiner disagrees with applicants' arguments regarding the deficiencies of the Vandecruys et al. reference for the reasons stated above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1-21 and 37 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 and 28 of copending

Application No. 10/821646 (actually it was mistyped as should have been 10/871646) is **withdrawn** in light of the abandonment of 10/871646 on March 10 2008.

The rejection of claims 26-29 ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 13 of copending Application No. 10871646 actually it was mistyped as should have been 10/871646) in view of Vandecruys et al. or Glinecke et al. is **withdrawn** in light of the abandonment of 10/871646 on March 10 2008.

Claims 1-12, 22-30, 37 and 48-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10626166 in view of . Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope.

The instant application claims a sustained-release pharmaceutical composition comprising reboxetine dispersed in a matrix comprising a hydrophilic polymer and a starch having a tensile strength of at least 0.15 kN/cm^2.

Copending '166 claims a sustained-release pharmaceutical composition comprising a water-soluble salt of pramipexole dispersed in a matrix comprising a hydrophilic polymer and a starch having a tensile strength of at least about 0.15 kN/cm^2. Copending '166 claims all the instant limitations in the dependent claims. As evidenced by the specification of Copending '166, pramipexole is a dopamine D_2 receptor agonist useful in the treatment of Parkinson's disease (page 1, paragraph 0005).

Copending '166 does not claim that the composition comprises reboxetine. However, this deficiency is cured by Lemke et al.

Lemke et al. is directed to the effect of Reboxetine on Depression in Parkinson's Disease patients. It is tuaght that depression occurs frequently in patients with Parkinson's diesease (page 300, background). A signigicant improvement in depression was seen with the administration of reboxetine with no significant changes in parkinsonian motor symptoms or dosages of levodopa (page 300 and 301, results).

It would have been obvious to one of ordinary skill in the art to combine the teachings of copending '166 and Lemke et al. and utilize reboxetine in the invention of copending '166. One of ordinary skill in the art would have been motivated to additionally add reboxetine as Lemke et al. teach that depression occurs frequently in patients with Parkinson's disease and that a significant improvement is seen in depression upon administration of reboxetine with no significant changes in dosages of levodopa with is utilized for parkinsonian motor symptoms. Since copending '166 teaches the use of pramipexole in the treatment of Parkinson's disease, one of ordinary skill in the art would have been motivated to further add reboxetine to aid in the treatment of the depression associated with Parkinson's disease.

Therefore, the scopes of the copending claims and the instant application overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to claims 1-12, 22-30, 37 and 48-58 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616